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MARSHALL, GERSTEIN & BORUN LLP
6300 SEARS TOWER
233 S. WACKER DRIVE
CHICAGO, IL 60606

EXAMINER	
BELYAVSKYI, MICHAIL A	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 05/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/006,557	KING ET AL.	
	Examiner	Art Unit	
	Michail A Belyavskyi	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *4-19,23-32 and 36-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,20-22 and 33-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-39 are pending.

2. Applicant's election of group I, claims 1-3, 20-22 and 33-35 in Response to Restriction Requirement, filed on 04/06/2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 4-19, 23-32 and 36-39 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

Claims 1-3, 20-22 and 33-35 drawn to a method of enhancing pericyte cell proliferation comprising administering to a subject in need a BPI protein product, wherein the subject is suffering from a complication of diabetes, under consideration in the instant application.

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention *to which the claims are directed.*

4. Applicant's submission of International Search Reports on the IDS, filed 10/11/02 has been considered, however said citation has been crossed out as it is not appropriate for printing in an issued patent.

5. The attempt to incorporate subject matter into this application by reference to Gray et al., on page 5, line 14 is improper because the sequence of BPI protein taught by Gray et al., is essential for prosecution of the instant application.

The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See In re Hawkins, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); In re Hawkins, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and In re Hawkins, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

An application as filed must be complete in itself in order to comply with 35 U.S.C. 112; however this does not bar incorporation by reference. Ex parte Schwarze, 151 USPQ 426 (Bd. of Appeals, 1966). An application for a patent when filed may incorporate "essential material" by reference to (1) a United States patent or (2) an allowed U.S. application, subject to the conditions set forth below. "Essential material" is defined as that which is necessary to (1) support the claims, or (2) for adequate disclosure of the invention (35 U.S.C. 112). "Essential material" may not be incorporated by reference to (1) patents or applications published by foreign countries or regional patent offices, to (2) non-patent publications, to (3) a U.S. patent or application which itself incorporates "essential material" by reference or to (4) a foreign application. See In re Fouche, 169 USPQ 429; 439 F.2d 1237 (CCPA 1971).

6 . The following is a quotation of the second paragraph of 35 U.S.C. 112.
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 2 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 2 recites the limitation " onset of diabetic retinopathy". There is insufficient antecedent basis for this limitation in the base claim 1. It is suggested that said claim be amended to be dependent from claim 3.

B. Claim 22 is indefinite and ambiguous in the recitation of " peptide is XMP.679". The use of " XMP.679 " as the sole means of identifying the claimed protein without providing SEQ ID NO for the protein is indefinite and ambiguous because different laboratories may use the same laboratory designations to define completely distinct protein.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 20-22 and 33-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of *in vitro* enhancing pericyte cell proliferation comprising culturing cells in the presence of BPI protein product wherein BPI protein product are XMP.627 (SEQ ID NO:4) or XMP.664 (SEQ ID NO:5) or XMP.679 (SEQ ID NO:3) or

XMP.728 (SEQ ID NO:6) or $rBPI_{21}$ does not reasonably provide enablement for (i) a method of *in vivo* enhancing pericyte cell proliferation comprising administering to a subject in need an amount of *any* BPI protein product, claimed in claims 1-3; or (ii) a method of *in vivo* enhancing pericyte cell proliferation comprising administering to a subject in need an amount of *any* BPI protein product wherein the BPI protein product is *any* amino-terminal fragment of BPI protein having a molecular weight of about 20kDa to 25 kDa, claimed in claim 20; or wherein BPI protein product is any BPI-derived peptide, claimed in claim 21; or (iii) a method of *in vivo* enhancing pericyte cell proliferation in a subject with diabetes-induced retinal vascular permeability comprising administering to a subject in need an amount of *any* BPI protein product , claimed in claims 33-35. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification does not enable one of skill in the art to practice the invention as claimed without undue experimentation.

(A) The claims as written encompass the genus of BPI protein product sequences to be used in a method of enhancing pericyte cell proliferation. The genus encompasses peptides wherein such peptides have numerous differences in amino acid sequences.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the limited working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

The specification only discloses detailed *in vitro* data on the ability of specific BPI protein products such as XMP.627 (SEQ ID NO:4) or XMP.664 (SEQ ID NO:5) or XMP.679 (SEQ ID NO:3) or XMP.728 (SEQ ID NO:6) or $rBPI_{21}$ to enhanced pericyte cell proliferation (see example 2 in particular) and in vivo data indicating that XMP.679 (SEQ ID NO:3) inhibits retinal neovascularization in a dose responsive manner (see example 4 in particular). The specification does not adequately teach how to effectively enhanced *in vivo* pericyte cell proliferation by administering to a subject in need an amount of *any* BPI protein product, as claimed in claims 1-3; or (ii) by administering to a subject in need an amount of *any* BPI protein product wherein the BPI protein product is *any* amino-terminal fragment of BPI protein having a molecular weight of about 20kDa to 25 kDa, claimed in claim 20; or wherein BPI protein product is *any* BPI-derived peptide, claimed in claim 21; or (iii) how to effectively enhanced *in vivo* pericyte cell proliferation in a subject with diabetes-induced retinal vascular permeability comprising administering to a subject in need an amount of *any* BPI protein product , claimed in claims 33-35. Moreover, no animals models were used to study the effectively of *in vivo* enhancing pericyte cell proliferation comprising administering to a subject in need an amount of *any* BPI protein product, claimed in claims 1-3; or (ii) *in vivo* enhancing pericyte cell

proliferation comprising administering to a subject in need an amount of *any* BPI protein product wherein the BPI protein product is *any* amino-terminal fragment of BPI protein having a molecular weight of about 20kDa to 25 kDa, claimed in claim 20; or wherein BPI protein product is any BPI-derived peptide, claimed in claim 21; or (iii) *in vivo* enhancing pericyte cell proliferation in a subject with diabetes-induced retinal vascular permeability comprising administering to a subject in need an amount of *any* BPI protein product , claimed in claims 33-35. Since there is no animal model studies and data in the specification to show the effectively *in vivo* enhancing pericyte cell proliferation comprising administering to a subject in need an amount of *any* BPI protein product, claimed in claims 1-3; or (ii) *in vivo* enhancing pericyte cell proliferation comprising administering to a subject in need an amount of *any* BPI protein product wherein the BPI protein product is *any* amino-terminal fragment of BPI protein having a molecular weight of about 20kDa to 25 kDa, claimed in claim 20; or wherein BPI protein product is any BPI-derived peptide, claimed in claim 21; or (iii) *in vivo* enhancing pericyte cell proliferation in a subject with diabetes-induced retinal vascular permeability comprising administering to a subject in need an amount of *any* BPI protein product , claimed in claims 33-35, it is unpredictable how to correlate *in vitro* results with *in vivo* use. Moreover, US Patent 5,856,302 (IDS) disclosed *in vivo* use of BPI protein product , its derivatives and fragments for treatment of angiogenesis and for inhibition of cell proliferation (see entire documents, overlapping columns 4 and 5 in particular). Feldman et al (Transplant. Proc. 1998, 30, 4126-4127) teach that "while it is not difficult to study the pathogenesis of animal models of disease, there are multiple constraints on analyses of the pathogenesis of human disease, leading to interesting dilemmas such as how much can we rely on and extrapolate from animal models in disease". In addition, Cochlovius et al (Modern Drug Discovery, 2003, pages 33-38) teach that in contrast to in vitro models, and partly animal-human xenograft systems, tissue cells in vivo seems to express molecules for defense against cellular immune systems as well as against complement. Although these defense mechanisms are still poorly understood, they provide some hints as to why many potential therapeutics perform marvelously in vitro but a fairly high portion of them still fail in vivo

An effective protocol for *in vivo* enhancing pericyte cell proliferation comprising administering to a subject in need an amount of *any* BPI protein product, claimed in claims 1-3; or (ii) *in vivo* enhancing pericyte cell proliferation comprising administering to a subject in need an amount of *any* BPI protein product wherein the BPI protein product is *any* amino-terminal fragment of BPI protein having a molecular weight of about 20kDa to 25 kDa, claimed in claim 20; or wherein BPI protein product is any BPI-derived peptide, claimed in claim 21; or (iii) *in vivo* enhancing pericyte cell proliferation in a subject with diabetes-induced retinal vascular permeability comprising administering to a subject in need an amount of *any* BPI protein product , claimed in claims 33-35 in the absence of *in vivo* data are unpredictable for the following reasons: (1) the BPI protein product may be inactivated before producing an effect, i.e. such as proteolytic degradation, immunological inactivation or due to an inherently short half-life of the protein; (2) the BPI protein product may not reach the target area because, i.e. the BPI protein product may not be able to cross the mucosa or the BPI protein product may be adsorbed by fluids, cells and tissues where the antibody has no effect; and (3) other functional properties, known or unknown, may make the protein unsuitable for in vivo therapeutic use, i.e. such as

adverse side effects prohibitive to the use of such treatment. See page 1338, footnote 7 of Ex parte Aggarwal, 23 USPQ2d 1334 (PTO Bd. Pat App. & Inter. 1992

The specification does not teach how to extrapolate data obtained from *in vitro* studies to the development of effective *in vivo* mammalian including human therapeutic treatment, commensurate in scope with the claimed invention. Therefore, it is not clear that the skilled artisan could predict the efficacy of a method of *in vivo* enhancing pericyte cell proliferation comprising administering to a subject in need an amount of *any* BPI protein product, claimed in claims 1-3; or (ii) a method of *in vivo* enhancing pericyte cell proliferation comprising administering to a subject in need an amount of *any* BPI protein product wherein the BPI protein product is *any* amino-terminal fragment of BPI protein having a molecular weight of about 20kDa to 25 kDa, claimed in claim 20; or wherein BPI protein product is any BPI-derived peptide, claimed in claim 21; or (iii) a method of *in vivo* enhancing pericyte cell proliferation in a subject with diabetes-induced retinal vascular permeability comprising administering to a subject in need an amount of *any* BPI protein product , claimed in claims 33-35. Moreover, Applicant himself acknowledge that the ability of BPI protein products to stimulate proliferation of pericytes was unexpected (page 12, line 25-30 of the Specification as filed) . As such, the invention must be considered unpredictable. Thus in the absence of working examples or detailed guidance in the specification, the intended uses: (i) of any BPI protein product or *any* amino-terminal fragment of BPI protein having a molecular weight of about 20kDa to 25 kDa or *any* BPI-derived peptide, for effectively enhancing *in vivo* pericyte cell proliferation or for enhanced *in vivo* pericyte cell proliferation in a subject with diabetes-induced retinal vascular permeability are fraught with uncertainties.

Also an issue that Applicant discloses a specific BPI protein products such as XMP.627 (SEQ ID NO:4) or XMP.664 (SEQ ID NO:5) or XMP.679 (SEQ ID NO:3) or XMP.728 (SEQ ID NO:6) or $rBPI_{21}$ that can be used for *in vitro* enhancing pericyte cell proliferation in the instant specification. Applicant has not taught how to make and/or use of *any* BPI protein product or *any* amino-terminal fragment of BPI protein having a molecular weight of about 20kDa to 25 kDa or *any* BPI-derived peptide, for effectively enhancing *in vivo* pericyte cell proliferation or for enhanced *in vivo* pericyte cell proliferation in a subject with diabetes-induced retinal vascular permeability. The structural and functional characteristics of said peptides are not defined in the claim. Applicant has not provided sufficient biochemical information (e.g. structural characteristics, amino acid composition , physicochemical properties, etc) that distinctly identifies *any* BPI protein product or *any* amino-terminal fragment of BPI protein having a molecular weight of about 20kDa to 25 kDa or *any* BPI-derived peptide other than a specific BPI protein products such as XMP.627 (SEQ ID NO:4) or XMP.664 (SEQ ID NO:5) or XMP.679 (SEQ ID NO:3) or XMP.728 (SEQ ID NO:6) or $rBPI_{21}$ that can be used for *in vitro* enhancing pericyte cell proliferation in the instant specification. Since the instant fact pattern fails to indicate that representative number of structurally related compounds is disclosed, the artisan would not know the identity of a reasonable number of representative compounds falling within the scope of the instant claims and consequently would not know how to make them.

Moreover, Applicant himself acknowledge that not any fragments of BPI will have the same activity as XMP.679 (SEQ ID NO:3) and further that not *any* BPI protein will have the ability of enhancing pericyte cell proliferation (see page 5, lines 20-31 and page 28, lines 15-20 in particular). In addition, the Specification disclosed that some of BPI protein products may have toxicity effects (see page 31, lines 5-15 in particular). Because of cytotoxicity effects of BPI protein products , US Patent ' 302 teaches the *in vivo* use of the same BPI protein product , its derivatives and fragments for treatment of angiogenesis and for inhibition of cell proliferation.

Protein chemistry is probably one of the most unpredictable areas of biotechnology . It is known in the art that even single amino acid changes or differences in a proteins amino acid sequence can have dramatic effects on the protein's function. For example, Mikayama et al. (PNAS, 1993. 90: 10056-10060) teach that the human glycosylation factor (GIF) protein differs from human macrophage migration inhibitory factor (MIF) by a single amino acid residue (see Figure 1 in particular). Yet, Mikayama et al. further teach that GIF is unable to carry out the function of MIF and MIF does not demonstrate GIF activity (see Abstract in particular). Burgess et al (J Cell Biol. 111:2129-2138, 1990) show that a conservative replacement of a single "lysine" reside at position 118 of acidic fibroblast growth factor by "glutamic acid" led to the substantial loss of heparin binding, receptor binding and biological activity of the protein. Similarly, Lazar et al. (Mol Cell Biol. 8:1247-1252, 1988) teach that in transforming growth factor alpha, replacement of aspartic acid at position 47 with alanine or asparagines did not affect biological activity while replacement with serine or glutamic acid sharply reduced the biological activity of the mitogen. These references demonstrate that even a single amino acid substitution or what appears to be an inconsequential chemical modification will often dramatically affect the biological activity and characteristic of a protein. Furthermore, the specification fails to teach what deletions, truncations, substitutions and mutations of the disclosed sequence can be tolerated that will allow the protein to function as claimed. While it is known that many amino acid substitutions are possible in any given protein, the position within the protein's sequence where such amino acid substitutions can be made with reasonable expectation of success are limited. Certain positions in the sequence are critical to the three-dimensional structure/function relationship, and these regions can tolerate only conservative substitutions or no substitutions.

Since the amino acid sequence of a polypeptide determined its structural and functional properties, predictability of which fragments will retain functionality requires knowledge of, and guidance with regard to, which amino acids in the polypeptide's sequence contribute to its structure, and therefore, function. The problem of predicting which fragments or derivatives of a protein will retain functionality and which will not is complex and well outside the realm of routine experimentation. Because of the lack of sufficient guidance and predictability in determining which structures would lead to functional proteins or peptides with the desired properties and that the relationship between the sequence of a peptide and it's tertiary structure (i.e. its activity) was not well understood and was not predictable (e.g. see Ngo et al, in The Protein Folding Problem and Tertiary Structure Prediction, 1994. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495.); it would require an undue amount of experimentation for one of skill in

the art to arrive at the breadth of proteins encompassed by the claimed invention. Without sufficient guidance, the changes which can be made in the structure of *any* BPI protein product or *any* amino-terminal fragment of BPI protein having a molecular weight of about 20kDa to 25 kDa or *any* BPI-derived peptide and still specifically enhancing pericyte cell proliferation is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue

Thus, Applicant has not provided sufficient guidance to enable one skill in the art to use claimed method of *in vivo* enhancing pericyte cell proliferation comprising administering to a subject in need an amount of *any* BPI protein product, claimed in claims 1-3; or (ii) a method of *in vivo* enhancing pericyte cell proliferation comprising administering to a subject in need an amount of *any* BPI protein product wherein the BPI protein product is *any* amino-terminal fragment of BPI protein having a molecular weight of about 20kDa to 25 kDa, claimed in claim 20; or wherein BPI protein product is any BPI-derived peptide, claimed in claim 21; or (iii) a method of *in vivo* enhancing pericyte cell proliferation in a subject with diabetes-induced retinal vascular permeability comprising administering to a subject in need an amount of *any* BPI protein product , claimed in claims 33-35 in manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement. *In re Fisher*, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

In view of the quantity of experimentation necessary, the unpredictability of the art, the lack of sufficient guidance in the specification, the limited working examples, and the limited amount of direction provided given the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

9. Claims 1-3, 20-22 and 33-35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of : a method of *in vitro* enhancing pericyte cell proliferation comprising culturing cells in the presence of BPI protein product wherein BPI protein product are XMP.627 (SEQ ID NO:4) or XMP.664 (SEQ ID NO:5) or XMP.679 (SEQ ID NO:3) or XMP.728 (SEQ ID NO:6) or $rBPI_{21}$.

Applicant is not in possession of :_(i) a method of *in vivo* enhancing pericyte cell proliferation comprising administering to a subject in need an amount of *any* BPI protein product, claimed in claims 1-3; or (ii) a method of *in vivo* enhancing pericyte cell proliferation comprising administering to a subject in need an amount of *any* BPI protein product wherein the BPI protein product is *any* amino-terminal fragment of BPI protein having a molecular weight of about

20kDa to 25 kDa, claimed in claim 20; or wherein BPI protein product is any BPI-derived peptide, claimed in claim 21; or (iii) a method of *in vivo* enhancing pericyte cell proliferation in a subject with diabetes-induced retinal vascular permeability comprising administering to a subject in need an amount of *any* BPI protein product , claimed in claims 33-35 .

The claimed invention is drawn to a genus of BPI protein product that can be used for a method for enhancing pericyte cell proliferation, however, structural identifying characteristics of the genus are not disclosed. Applicant has disclosed only XMP.627 (SEQ ID NO:4) or XMP.664 (SEQ ID NO:5) or XMP.679 (SEQ ID NO:3) or XMP.728 (SEQ ID NO:6) or $rBPI_{21}$. It is noted that all disclosed BPI proteins have different structure. Applicant has not provided sufficient information that distinctly identifies the common structure of the disclosed BPI proteins to be used for the method of enhancing pericyte cell proliferation. Thus there is no evidence that there is any *per se* structure/function relationship between the disclosed BPI protein of different structure and any others that might be found using the claimed method.

A description of a protein by functional language in the absence of a structure is not considered sufficient to show possession of the claimed invention. A description of what a material does rather than of what it is, usually does not suffice. See Fiers, 984 F.2d at 1169-71, 25 USPQ2D at 1605-06. It is only a definition of a useful result rather than a definition of what achieves that result. Many species may achieve that result. The definition requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 /f.2d 1516, 1521, 22 USPQ 369, 372-73 (Fed. Cir. 1984) affirming the rejection because the specification does "little more than outline[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what the material consists of (e.g. structural feature), is not a description of that material.

Applicant has disclosed a limited number of species each having different structure , therefore, the skilled artisan cannot envision all the contemplated amino acid sequence possibilities recited in the instant claims. Consequently, conception in either case cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. The sequences themselves are required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993).

A description of a genus of protein sequences may be achieved by means of a recitation of a representative number of polypeptide sequences, defined by amino acid sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. Regents of the University of California v. Eli Lilly&Co., 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).
Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry,

whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

10. No claim is allowed.

11. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michail Belyavskyi, Ph.D.
Patent Examiner
Technology Center 1600
May 17, 2004

Christina Chan

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600